REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Claims 21-41, including independent claims 21, 36, 37, and 39, are currently pending in the present application. Claims 1-20 were previously cancelled, while claims 21 and 36-39 are currently being amended.

Independent claim 21, for instance, is directed to a medical packaging substrate comprising a polymer-impregnated paper-based web. The web is saturated with a saturant comprising a polymer emulsion having a glass transition temperature of -20°C or less. The saturant is present at an add-on level of from about 20 to about 80 dry parts per 100 dry parts of fiber in the polymer-impregnated paper-based web. The polymer-impregnated web has a percent bacterial filtration efficiency ("%BFE") of at least about 95%.

In the Office Action, claims 21-34 were rejected under 35 U.S.C. § 112, first paragraph; as failing the comply with the written description requirement. The Office Action stated that "support for the saturant being present at an add-on level of from about 20 to about 80 dry parts per 100 dry parts of fibers is not found in the Applicants' specification."

Applicants respectfully submit that the claims of the present application meet all of the requirements of Section 112, first paragraph. For example, the limitations in all the independent claims regarding the add-on level of the saturant in dry parts, per dry parts of fiber in the web, find support in Applicants' specification at page 17, line 20 through page 18, line 12, in the Examples at page 19, lines 7-10, and in original claims 5 and 6. Accordingly, Applicants respectfully submit that claims 21-41 properly comply with 35 U.S.C. § 112, first paragraph.

Further, in the Office Action, claims 21-41 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over claims 1-5 of U.S. Patent No. 6,743,522 to Bean, et al. Without commenting on the propriety of this rejection, Applicants agree to submit a Terminal Disclaimer pursuant to

37 C.F.R. § 1.321 when the claims of the present application are otherwise deemed allowable.

Additionally, in the Office Action, independent claims 21, 36, and 37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,677 to Brown Reed, et al. Brown Reed, et al. relates to a medical packaging substrate material that may be sterilized by an oxidizing gas plasma. The material may include a cellulosic nonwoven web applied with a saturant at a level of from about 50 to about 150 weight % based on the dry weight of the fibers. The saturant may include, for instance, poly(vinylidene chloride)-acrylonitrile-butyl acrylate copolymer, a mixture of such a polymer with a carnauba wax emulsion, or a mixture of a poly(vinylidene chloride) acrylate copolymer and a carnauba wax emulsion. (Col. 2, lines 33-51). As correctly noted by the Examiner, Brown Reed, et al. fails to disclose (1) the use of a polymer emulsion having a glass transition temperature of -20°C or less and (2) Applicants' claimed percent bacterial filtration efficiency (%BFE) of at least about 95%. Nevertheless, it was asserted that such a claimed %BFE value was ***inherent*** to the disclosure of Brown Reed, et al. (See Office Action, at 5).

In response to this "inherency" rejection, Applicants have submitted two Affidavits Under 37 CFR § 1.132—(1) a June, 2003 Affidavit of Ms. Karen H. Bean, which established that the %BFE of the product of Brown Reed, et al. was outside Applicants' claimed %BFE range; and (2) a February, 2004 Affidavit of Dr. Jay R. Sommers, which established that Applicants' claimed %BFE represents a significant improvement over the %BFE found in Brown Reed, et al. Accordingly, these Affidavits establish overwhelming evidence that Applicants' claimed %BFE range is not inherent to the disclosure of Brown Reed, et al.

However, in the Response to Arguments section, the instant Office Action stated the following:

> Applicants are reminded that the anticipation issues cannot be overcome by the affidavits under 37 CFR 1.132. And again, the examiner maintains that it is immaterial that the claim recites a property of the composition claimed that is not disclosed in the prior art where the prior art composition is the same as that claimed. Accordingly, the art rejections over Brown Reed are thus sustained.

(Office Action, at 10). Applicants respectfully disagree with these assertions in the Office Action.

First, 37 CFR § 1.132 clearly states that "when **any** claim of an application or a patent under reexamination **is rejected or objected to**, **any evidence** submitted to traverse the rejection or objection **on a basis not otherwise provided for** must be by way of an oath or declaration under this section." (Emphases added). Section 132 does not state that its provisions are inapplicable to rejections under 35 U.S.C. § 102. Rather, MPEP § 2112, which describes the requirements of rejections based on inherency, explicitly talks about declarations filed by patent applicants to overcome Section 102 rejections based on inherency. (See, e.g., MPEP § 2112, at V., discussing In re Schreiber, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997) and the types of evidence the patent applicant should have included in a **declaration** to overcome an anticipation rejection based on inherency).

In the present case, Applicants have done exactly what is suggested in portions of the MPEP like Sections 2112, 2112.01, 2112.02, and 2113 that describe ways to overcome a Section 102 rejection based on inherency—namely, Applicants have provided **concrete, objective evidence** showing that the prior art product, here the product of Brown Reed et al., **does not *necessarily possess* the characteristics of the claimed product**, here the claimed percent bacterial filtration efficiency of at least about 95%. (See MPEP § 2112.01, at I.). Thus, Applicants respectfully submit that independent claims 21, 36, and 37 patentably define over Brown Reed, et al.

Moreover, independent claims 21, 36, 37, and 39 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,692,374 to Bouchette. Bouchette is directed to an antimicrobially active, nonwoven web and a wet wiper that contains the web. The web of Bouchette is (1) applied throughout with an uncured binder, (2) applied throughout with an antimicrobial agent, preferably an organo-silicon quaternary ammonium salt, and (3) cured so that the binder material binds the fibers together. The Office Action stated that the claimed glass transition temperature range for Applicants' claimed polymer emulsion would be "inherently present" in Bouchette. The Office Action

additionally stated that Applicants' claimed %BFE would be "inherently present" in Bouchette.

Applicants respectfully submit that the present claims patentably define over Bouchette. Bouchette completely fails to disclose or suggest a medical packaging substrate according to the present claims. Applicants' claimed medical packaging substrates are specifically designed to allow for surgical instruments contained therein to become sterilized, while simultaneously acting as a good barrier to bacteria. Additionally, Bouchette completely fails to disclose or suggest the use of a polymer emulsion having a glass transition temperature of -20°C or less. Rather, the only commercially available examples given in Bouchette for its "uncured binder" *do not have* a glass transition temperature within the claimed range of less than about -20°C. Specifically, Applicants understand that Airflex A-410 and Airflex A-106 binders (Air Products, Inc., see col. 4, lines 25-41) have glass transition temperatures of +4°C and 0°C, respectively. Likewise, Applicants understand that HA-8 binder (Rohm & Haas, see col. 4, lines 25-42) has a glass transition temperature of -10°C. Accordingly, Applicants respectfully submit that Bouchette fails to disclose or suggest a polymer emulsion having a glass transition temperature of -20°C or less.

Applicants also respectfully submit that the medical packaging substrates of the present claims are not taught or suggested by Bouchette because Applicants' claimed percent bacterial filtration efficiency of at least about 95% is not "inherently present" in Bouchette. To establish inherency, the evidence must make clear that the missing descriptive matter is ***necessarily present*** in the reference, and that it would be so recognized by persons of ordinary skill in the art. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Thus, an inherency rejection may not be based on what would result due to the optimization of conditions, but only on what was ***necessarily present*** in the prior art.

In the instant case, numerous aspects of the Applicants' medical packaging substrate may be altered to influence its %BFE, e.g., the type of saturant polymers utilized, the add-on level, the type of web, and so forth. Thus, to obtain the claimed

properties, one of ordinary skill would have to select from numerous possible conditions and parameters. And there is simply no indication that the antimicrobially active, nonwoven web of Bouchette, with its specific uncured binder, its specific antimicrobial agent containing an organo-silicon quaternary ammonium salt, and its specific curing step, would **necessarily exhibit** a percent bacterial filtration efficiency within Applicants' claimed range, *particularly* where each example of a latex binder given in Bouchette simply does not have a glass transition temperature of -20°C or less. Consequently, Applicants respectfully submit that the claimed properties do not necessarily flow from the teachings of the cited reference and that claims 21, 36, 37, and 39 patentably define over Bouchette.

Lastly, independent claims 21, 36, 37, and 39 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,191,734 to Weber, et al. Weber, et al. describes a material for use in agricultural mulch and row covers, bags, outer covers for personal care products (e.g., diapers, feminine pads, training pants, incontinence products, and wound dressings), surgical drapes, and gowns. The Office Action recognizes that Weber, et al. fails to explicitly disclose Applicants' claimed %BFE, but asserts that Applicants' claimed %BFE would be "inherently present" in the disclosure of Weber, et al.

Again, Applicants respectfully submit that the products disclosed by Weber, et al. differ substantially from the medical packaging substrate of the present claims, which is specifically designed to allow for surgical instruments contained therein to become sterilized, while simultaneously acting as a good barrier to bacteria. Additionally, Applicants respectfully submit that Weber, et al. completely fails to disclose or suggest Applicants' claimed %BFE range for its medical packaging substrate. Again, Applicants emphasize that, to establish inherency, the evidence must make clear that the missing descriptive matter is ***necessarily present*** in the reference, and that it would be so recognized by persons of ordinary skill in the art. There is no indication that Applicants' claimed %BFE range would ***necessarily*** be exhibited by the biodegradable latex web materials of Weber, et al., particularly in light of the Affidavits Under 37 CFR § 1.132 that have already been submitted in this case, which demonstrate that actual medical

packaging substrate materials (like those of Brown Reed, et al.) have been tested and have exhibited significantly reduced %BFE values outside of Applicants' claimed range. Consequently, Applicants respectfully submit that the claimed properties of the medical packaging substrate of the pending claims do not necessarily flow from the teachings of the cited reference and that independent claims 21, 36, 37, and 39 patentably define over Weber, et al.

Applicants also respectfully submit that, at least for the reasons indicated above relating to the corresponding independent claims 21, 36, 37, and 39, dependent claims 22-35, 38, and 40-41 patentably define over the references cited. However, Applicants also note that the patentability of dependent claims 22-35, 38, and 40-41 does not necessarily hinge on the patentability of the respective independent claims. In particular, some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Vo is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,
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